K002414

SEP 25 2000

Fisher & Paykel Healthcare Ltd
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East Tamaki
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New Zealand
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4 510(K) SUMMARY

Contact person	Brett Whiston
Date prepared	August 03 2000
Trade name	Phototherapy System
Common name	Phototherapy Lamp
Classification name	Neonatal Phototherapy Unit (21 CFR § 880.5700)
Predicate device	Medela Phototherapy Lamp 510(k) # K984589

Description of device

The Fisher & Paykel Phototherapy System is a modification to the predicate Medela Phototherapy Lamp so that it can be used specifically with the Fisher & Paykel Cosycot Infant Warmers (510(k) # K971695, K972885). It consists of the unchanged Medela Lamp head containing the fluorescent tubes, a reconfigured power module, and new support structure.

The Phototherapy Lamp head mounts onto the column of the Cosycot Infant Warmer and can have its distance from the baby adjusted. The Phototherapy Power Module controls the power delivered to the fluorescent tubes and must connect to the Infant Warmer Power Module to draw 120 V~ 60 Hz mains power.

Intended use

The Phototherapy System treats neonates with hyperbilirubinaemia by skin irradiation from fluorescent blue light. A medical practitioner administers treatment in a hospital. It has the same intended use as the predicate Medela device.

Technological Characteristics

The technological characteristics are identical to the predicate device for both the phototherapy head and power module.

- Blue fluorescent light over wavelength 420 to 480 nm
- Light effectiveness monitoring
- No spread of light
- Very low energy consumption
- Silent operation
- Versatile swivelling and adjustment

Standards

The Fisher & Paykel Phototherapy System conforms to IEC 60601-1:1988 and national variants including UL 2601-1.

Biocompatibility

Touchable surfaces on the Phototherapy Lamp head are the same as the predicate Medela device. Touchable surfaces on the Power Module are the same as those of the currently marketed Cosycot Infant Warmer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2000

Mr. Brett Whiston
Regulatory Affairs Engineer
Fisher & Paykel Healthcare, Limited
15 Maurice Paykel Place
East Tamaki
P.O Box 14 348
Panmure, Auckland
NEW ZEALAND

Re: K002414
Trade Name: Phototherapy System
Regulatory Class: II
Product Code: LBI
Dated: August 3, 2000
Received: August 7, 2000

Dear Mr. Whiston:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

For Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002414

3 INDICATIONS FOR USE STATEMENT

510(K) Number _____

Device Trade Name Phototherapy System

The Fisher & Paykel Healthcare Phototherapy System is for the treatment of excessive serum-bilirubin in newborn babies.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(per 21 CFR 801.109)

Anne Naveau for PXC 9/22/00

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 002414